UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MILADY AQUINO,	)	
	)	
Plaintiff,	)	No. 18-cv-5291
	)	
v.	)	Judge Thomas M. Durkin
	)	
C.R. BARD, INC.; BECTON DICKINSON AND COMPANY; BOSTON SCIENTIFIC CORPORATION; and CAMBRIDGE POLYMER GROUP, INC.	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Milady Aquino filed this products liability action against defendants C.R. Bard, Inc. and Becton Dickinson and Company[1] (together, "Bard"), Boston Scientific Corporation ("BSC"), and Cambridge Polymer Group, Inc. ("Cambridge") seeking relief following the implantation of Bard transvaginal and BSC transabdominal pelvic mesh products.[2] Each of the defendants moved to dismiss some

[1] Becton Dickinson and Company purchased C.R. Bard, Inc. on December 29, 2017, and is its successor in interest. R. 66 ¶ 4.

[2] This case is similar to thousands of cases filed against Bard and BSC (among others) in which plaintiffs seek relief in connection with the implantation of various transvaginal pelvic mesh products. By 2012, the United States Judicial Panel on Multi-District Litigation ("JPML"), pursuant to 28 U.S.C. § 1407, consolidated and transferred all federal transvaginal pelvic mesh cases pending to the Honorable Joseph R. Goodwin in the United States District Court for the Southern District of West Virginia for coordinated pre-trial proceedings (the "MDLs"). On June 21, 2018, Judge Goodwin ordered that the JPML cease the transfer of cases and that plaintiffs no longer directly file claims in the MDLs. *See* MDL No. 2187, June 21, 2018 order. This case was filed about two months later. Bard represented at oral argument that had the MDLs continued to accept cases, Aquino's case against Bard likely would have been part of one. But because the BSC device at issue is a transabdominal,

or all of the claims against it under Federal Rule of Civil Procedure 12(b)(6). For the following reasons, BSC's, Bard's and Cambridge's motions are granted.

STANDARD

A Rule 12(b)(6) motion challenges the "sufficiency of the complaint." *Berger v. Nat. Collegiate Athletic Assoc.*, 843 F.3d 285, 289 (7th Cir. 2016). A complaint must provide "a short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), sufficient to provide defendant with "fair notice" of the claim and the basis for it. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). This standard "demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). While "detailed factual allegations" are not required, "labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. The complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). "'A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Boucher v. Fin. Sys. of Green Bay, Inc.*, 880 F.3d 362, 366 (7th Cir. 2018) (quoting *Iqbal*, 556 U.S. at 678). In applying this standard, the Court accepts all well-pleaded facts as true and draws all reasonable inferences in favor of the non-moving party. *Tobey v. Chibucos*, 890 F.3d 634, 646 (7th Cir. 2018).

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rather than transvaginal, device, BSC believes Aquino's case against it would not have been included.

BACKGROUND

This case involves two surgical mesh products used to treat urogynecologic conditions: BSC's Upsylon Traditional Y Mesh, and Bard's Align™ Urethral Support System (respectively, "BSC Device" and "Bard Device," and together, "Defendants' Mesh Products"). Defendants' Mesh Products were implanted in Milady Aquino in July 2016 via differing methods, into different areas of her body, to serve different purposes. That is, the BSC Device was implanted transabdominally outside the vagina to treat pelvic organ prolapse ("POP"), and the Bard Device was implanted transvaginally inside the vagina to treat stress urinary incontinence.

FDA and industry communications regarding transvaginal mesh. Transvaginal mesh had been the subject of scrutiny for years prior to Aquino's implantation procedure. In July 2011, the FDA issued a statement indicating that "serious complications associated with surgical mesh for transvaginal repair of POP" were "not rare," and identifying mesh "contraction (shrinkage)" as associated with vaginal shortening, tightening and pain, and as a previously unidentified risk ("FDA Safety Communication"). SAC ¶¶ 11-12 (emphasis in original).[3] According to the FDA Safety Communication, it was "not clear" that transvaginal POP repair with mesh was more effective than non-mesh repair, and such mesh repair "may expose patients to greater risk." *Id.* ¶ 14.

[3] "SAC" refers to Aquino's Second Amended Complaint, appearing at Docket Number 66, which is the subject of Defendants' motions.

The FDA contemporaneously published "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" ("FDA White Paper"), which also noted the "serious adverse events" and "complications" associated with transvaginal mesh for POP repair, and the lack of evidence that transvaginally placed mesh "improves clinical outcomes any more than traditional POP repair." *Id.* ¶¶ 15-18.

Later in 2011, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") issued a Joint Committee Opinion noting "increasing reports" of vaginal pain associated with vaginal mesh "contraction, retraction, or shrinkage" ("ACOG/AUGS Joint Committee Opinion"). *Id.* ¶ 20. It warned that some women "require surgical intervention" and that pain may be intractable, and recommended vaginal mesh repair only in "high-risk individuals in whom the benefit . . . may justify the risk." *Id.* ¶¶ 20-21.

Polypropylene used in Defendants' Mesh Products. Defendants' Mesh Products were initially constructed from Marlex HGX-030-01 ("Marlex"), a specific polypropylene manufactured and trademarked by a joint venture between Chevron and Phillips Sumika ("Phillips") in Texas, and sold in its raw form in pellets. *Id.* ¶¶ 55-56, 59. At all relevant times, Marlex's Material Safety Data Sheet ("MSDS") warned that Marlex should not be used for "permanent implantation in the human body or permanent contact with internal body fluids or tissues" unless "provided directly from Phillips . . . under an agreement which expressly acknowledges the contemplated use." *Id.* ¶¶ 59-60.

At a certain point, Phillips stopped selling Marlex to Bard and BSC. *Id.* ¶¶ 61, 63. Thereafter, Bard began purchasing Marlex from third parties, while BSC considered seeking FDA approval of a mesh made from a different polypropylene. *Id.* ¶¶ 62, 65, 67. But BSC ultimately concluded that the FDA was unlikely to approve the change given its "anti-mesh" position, and that even if it did, the process would take too long and impact BSC's profits too significantly. *Id.* ¶ 67. Accordingly, beginning in 2011, BSC also sought Marlex from third parties. *Id.*

In the end, BSC purchased a 25-year supply of raw polypropylene pellets from Chinese distributor EMAI Plastic Raw Materials Co., Ltd. ("EMAI") at well below market price ("Chinese polypropylene"). *Id.* ¶¶ 68, 74, 78, 91. BSC learned from Phillips that the lot number on the bags EMAI sold it—and which bore the Phillips/Marlex labels—was not genuine. *Id.* ¶¶ 76-79, 84-89, 91. EMAI also could not produce the Certificate of Compliance or the Certificate of Analysis that would have been required had EMAI imported genuine Marlex pellets from Phillips in the United States to EMAI in China. Nor could EMAI produce documentation either of any import tax paid, or to establish that the polypropylene had cleared Chinese customs—both of which would have occurred had the polypropylene originally shipped from the United States to China, and both of which were required in order to lawfully export from China a good that was originally manufactured elsewhere. *Id.* ¶¶ 80-81. Accordingly, BSC had to determine how to ship the undocumented goods to the United States for its use without raising any red flags. *Id.* ¶¶ 81, 92.

With this knowledge and in order to clear Chinese customs, BSC arranged to "over-bag" the bags of Chinese polypropylene pellets, placing them inside plain bags to cover up their Phillips/Marlex labels. *Id.* ¶ 96. BSC then split the shipment in three to reduce the risk of scrutiny, telling Chinese customs that the product was made by EMAI, and telling United States customs that the bags contained Marlex manufactured in Texas and returning to the United States for use. *Id.* ¶¶ 97-98, 100.

Cambridge, a research laboratory, performed various tests on the Chinese polypropylene at BSC's request. The testing categories differed from those used by Phillips for Marlex, and the tests themselves were not performed to industry standards. *Id.* ¶ 103. Ultimately, the tests revealed (among other things) that the Chinese polypropylene: (1) produced weaker fibers than Marlex; (2) had a different melt rate; and (3) contained high levels of selenium, an element that reacts with hydrogen peroxide to form an acid that attacks polypropylene. *Id.* ¶ 105. Cambridge's initial report to BSC stated that "[a]ll the samples showed high levels of selenium." *Id.* ¶ 106. The report referred to selenium as "rare and toxic" and the result as "unusual," and recommended that it be "verified using another technique." *Id.* BSC and Cambridge discussed the report by phone. Three days later, Cambridge issued an amended report, again indicating that "[a]ll the samples showed high levels of selenium," but omitting the "rare and toxic" characterization, and the suggestion for further testing. *Id.* ¶¶ 106-107. BSC mentioned neither the presence of selenium nor the additional testing Cambridge initially recommended in its own internal report. *Id.* ¶ 108.

About 5 years later in April 2016, Polymer Solutions—another laboratory—conducted additional testing on the same lots of Marlex and Chinese polypropylene. That testing demonstrated differences in the two products' additives. Specifically, that: (1) the Chinese polypropylene contained over a dozen chemicals that the Marlex did not, including an additive that was highly susceptible to ultraviolet degradation; and (2) although both the Marlex and Chinese polypropylene contained an additive designed to slow natural degradation of the polypropylene caused by peroxides, it was detected in significantly lower amounts in the Chinese polypropylene. *Id.* ¶¶ 120-122. Beginning in June 2011 and continuing until fall 2012, BSC incorporated the Chinese polypropylene into its mesh products. *Id.* ¶ 68.

Aquino's treatment with and complications from Defendants' Mesh Products. Aquino was implanted with the Bard Device transvaginally to treat urinary incontinence, and with the BSC Device transabdominally to treat POP in July 2016. *Id.* ¶¶ 2-3. The BSC Device implanted was constructed from Chinese polypropylene.[4] Aquino claims that Defendants' Mesh Products have caused numerous side effects and conditions, including: inability to void; urinary incontinence/leaking; urinary urgency and frequency; incomplete emptying of the bladder; severe pain with urination requiring her to stand when urinating; pelvic floor spasms; a chronic pain syndrome in the vagina, suprapubic area, perirectal area,

[4] Although the SAC does not explicitly say so, the Court assumes from the other allegations that the Bard Device implanted was constructed from Marlex purchased from third parties. *See* SAC ¶ 62 ("Bard . . . arrang[ed] for the purchase of Marlex . . . by third party companies, including Red Oaks, who then supplied Bard with Marlex").

pelvis and lower abdomen; recurrent urinary tract infections; bladder lesions; bladder spasms; loss of sexual activity; erosion, mesh contraction and wading; infection; fistula; inflammation; scar tissue; dyspareunia (pain during sexual intercourse); prolapse of female genital organs; neuropathic and other acute and chronic nerve damage; pelvic floor damage; and other associated symptoms and exacerbations of her medical conditions. *Id.* ¶ 23.

As a result, Aquino underwent procedures in February, September, October and December 2017, including a revision of her Bard Device. Aquino continues to require treatment for chronic conditions she claims are attributable to Defendants' Mesh Products. *Id.* ¶ 24.

Aquino's claims. Aquino initially filed her case in state court in June 2018. Bard and BSC timely removed her complaint in August 2018, and this Court denied Aquino's motion to remand. Aquino subsequently amended her complaint twice, including to remove her claim against BSC and Cambridge for violation of the Illinois Counterfeit Trademark Act, 765 ILCS 1040—a claim arising out of their conduct relative to the Chinese polypropylene. The SAC spans 64 pages and alleges a smorgasbord of claims: (1) negligence as to Bard (Count I); (2) strict liability – design defect as to Bard (Count II); (3) strict liability – manufacturing defect as to Bard (Count III); (4) strict liability – failure to warn as to Bard (Count IV); (5) breach of express warranty as to Bard (Count V); (6) breach of implied warranty as to Bard (Count VI); (7) willful and wanton misconduct as to Bard (Count VII); (8) negligence as to BSC (Count VIII); (9) strict liability – design defect as to BSC (Count IX); (10)

strict liability – manufacturing defect as to BSC (Count X); (11) strict liability – failure to warn as to BSC (Count XI); (12) breach of express warranty as to BSC (Count XII); (13) breach of implied warranty as to BSC (Count XIII); (14) willful and wanton misconduct as to BSC (Count XIV); (15) negligence as to Cambridge (Count XV); and (16) willful and wanton misconduct as to Cambridge (Count XVI). The Court held oral argument on Defendants' motions to dismiss at the parties' request, at which time Aquino voluntarily dismissed her claims for breach of implied warranty (Count VI as to Bard, and Count XIII as to BSC). Further, while Bard denies liability on Aquino's design defect claims (theories plead in Counts I and II), its motion takes no issue with them. The Court addresses the remaining claims below, beginning with those against BSC.

ANALYSIS

I. BSC's Motion to Dismiss

BSC argues that dismissal of the claims against it is proper for three reasons: (1) Aquino's claims are preempted and precluded; (2) Aquino's factual allegations overwhelmingly concern trans*vaginal* mesh, and cannot support claims regarding its trans*abdominal* mesh product at issue here; and (3) Aquino otherwise makes only formulaic recitations of her claims and thus fails to adequately plead them.

A. Preliminary Matters

The Court notes at the outset BSC's argument that because each of Aquino's claims against it incorporates by reference the factual allegations concerning Chinese polypropylene, each is premised only on the dangers of Chinese polypropylene, and

not the dangers of polypropylene implantation generally. This, BSC argues, means that to the extent claims regarding the Chinese polypropylene are preempted, Aquino's claims against it are barred. But the Court does not read the SAC so narrowly. Although far from a model of clarity, taking the allegations in the light most favorable to Aquino as it must, the Court finds that the SAC more than sufficiently alleges the dangers of polypropylene generally, and also incorporates those allegations in the claims against BSC. *See, e.g.*, SAC ¶ 9 ("scientific evidence shows that [polypropylene] . . . is biologically incompatible with human tissue" and "promotes inflammation of the pelvic tissue" and "can contribute to . . . severe adverse reactions"); *id.* ¶ 60 (quoting Marlex MSDS warning against the use of Marlex "in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues"). Accordingly, even if preempted to the extent based on Chinese polypropylene, Aquino's claims proceed because they also concern the dangers of polypropylene generally.

B. Preemption and Preclusion

A bit of background on the FDA's medical device approval process is necessary to understand the parties' preemption and preclusion arguments. Congress granted the FDA sole authority to regulate medical devices and created a "regime of detailed federal oversight" through the Medical Device Amendments Act of 1976, 21 U.S.C. § 360 (the "MDA"),which amended the Food, Drug, and Cosmetics Act ("FDCA"). *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327-30 (2008). The MDA divides medical devices into three categories based on the risk they pose to the public: (1) Class I devices, which

present no unreasonable risk of illness or injury; (2) Class II devices, which possess a greater potential dangerousness warranting more stringent controls; and (3) Class III devices, which "present[ ] a potential unreasonable risk of illness or injury," and are therefore subject to the most regulation. 21 U.S.C. § 360c(a)(1)(A)-(C).

Class III devices generally are required to undergo a "rigorous" premarket approval ("PMA") process. *Reigel*, 552 U.S. at 317. During that process, a manufacturer submits detailed information concerning the safety and efficacy of its device—typically in the form of a multivolume application—which the FDA then spends an average of 1,200 hours reviewing. *Id.* at 317-18. Once such a device has received premarket approval, the MDA prohibits its manufacturer from making changes that would impact safety or effectiveness without FDA permission. Such permission is typically granted through a supplemental PMA application "evaluated under largely the same criteria as an initial application." *Id.* at 319 (citing 21 U.S.C. § 360e(d)(6) and 21 CFR § 814.39(c)).

Nevertheless, many Class III devices, as well as all new Class I and II devices, are subject only to a "limited form of review" under which manufacturers submit a "premarket notification" to the FDA. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476-78 (1996). Known as the Section 510(k) process, the FDA's determination rests not on safety, but rather on a finding of substantial equivalence to an already-approved medical device. *Id.* 478, 493. It is "by no means comparable to the PMA process," and is completed in "an average of only 20 hours." *Id.* at 478-79. As such, Section 510(k) approval provides "little protection to the public." *Id.* at 493.

Both of Defendants' Mesh Products received FDA clearance for marketing under Section 510(k) as "substantially equivalent" to devices already on the market, and both were classified as Class II devices. But on March 31, 2016, a citizen petition was filed with the FDA concerning the Chinese polypropylene BSC had begun to use in certain products (the "Citizen Petition"). The Citizen Petition was the result of the decision in *Stevens v. Boston Scientific Corporation*, 152 F. Supp. 3d 527, 537 (S.D. W. Va. 2016), a putative class action asking the court to enjoin BSC from marketing, selling, or importing mesh products constructed from Chinese polypropylene. There, Judge Joesph Goodwin declined to order the injunctive relief requested and stayed and deferred the case to the FDA under the doctrine of primary jurisdiction. The court reasoned that deferral was appropriate because the plaintiff's allegations were "based on alleged violations of statutes and regulations over which the FDA exercises its expertise and impressive administrative dominance," and because the FDA was "in the best place to determine whether Boston Scientific's mesh device [was] in compliance with the FDA's own statutes, regulations, and directives." *Stevens*, 152 F. Supp. 3d at 537. Although it did not issue a formal response to the Citizen Petition, almost 18 months later, the FDA issued a public letter indicating among other things that BSC's "change in supplier" (from Phillips to EMAI) did not "raise new safety or effectiveness concerns," and the differences between Marlex and the Chinese

polypropylene did not "require submission of a new premarket notification" (the "FDA Letter").[5] R. 72, Ex. 5 at 1.

BSC argues that Aquino's claims against it fail because each is based on allegations concerning the safety of the Chinese polypropylene used in the BSC Device between 2011-2012—allegations considered and rejected by the FDA through the FDA Letter, and thereby expressly and impliedly preempting, and precluding, Aquino's claims. In response, Aquino contends that because the BSC Device received only 510(k) approval, no preemption lies, and that her claims concern the use of any polypropylene (not just the Chinese polypropylene) in any event. The Court addresses the parties' arguments below.

1. Preemption

Preemption is a doctrine rooted in the Constitution's Supremacy Clause that recognizes Congress's power to preempt or invalidate state laws through federal legislation. *Oneok, Inc. v. Learjet, Inc.*, 135 S. Ct. 1591, 1594-95 (2015). It may do so through express statutory language, or impliedly through either field preemption (not at issue here), or conflict preemption. *Id.* at 1595. "Conflict preemption exists where

[5] Notably, both BSC and Aquino attach documents to their briefs; Aquino includes 20 exhibits, and BSC includes 5. The Court can take judicial notice of both the Citizen Petition and the FDA Letter, which are attached to BSC's motion. *See Vincent v. Medtronic, Inc.*, 221 F. Supp. 3d 1005, 1007 (N.D. Ill. 2016) ("Executive and agency determinations are subject to judicial notice." (citing *Houston v. United States*, 638 Fed. Appx. 508, 514 (7th Cir. 2016))); *see also United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1062 n.14 (N.D. Cal. 2014) (taking judicial notice of FDA citizen petition). As explained *infra*, the Court has also considered some of the other exhibits in resolving these motions. Those documents not mentioned have been excluded.

the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress' or where 'compliance with both state and federal law is impossible.'" *Mullins v. Ethicon, Inc.*, 147 F. Supp. 3d 478, 480 (S.D. W. Va. 2015) (quoting *Oneok, Inc.*, 135 S. Ct. at 1595). But regardless of the form of preemption asserted, two principles guide the Court's analysis. First, the presumption against the preemption of state police power. *Lohr*, 518 U.S. at 475. And second, that Congress's purpose "is the ultimate touchstone in every preemption case." *Lohr*, 518 U.S. at 485. Here, BSC argues that both express and implied preemption apply to bar all claims against it.

Express preemption. BSC first argues that the claims against it are expressly preempted under Section 360k of the MDA. That section preempts state common law claims when: (1) the federal government has established specific requirements applicable to the device; and (2) the common law claims are based on state requirements that are "different from, or in addition to the federal ones" and relate to the device's safety and effectiveness.[6] *Riegel*, 552 U.S. at 322 (citing 21 U.S.C. § 360k(a)).

[6] The MDA specifically provides that no state:

> may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

Here, the dispute centers around the first prong of this test; that is, whether there existed any federal "requirement" applicable to the BSC Device. The United States Supreme Court has expressly distinguished between devices subject to the safety and efficacy scrutiny involved in the PMA process and those subject to 510(k) "equivalency" approval for purposes of analyzing Section 360k's reach. Indeed, the Supreme Court held in *Riegel* that the PMA process imposes device-specific "requirements" concerning safety sufficient to invoke Section 360k preemption, but held in *Lohr* that the Section 510(k) process does not. *See Riegel*, 552 U.S. at 323-26; *Lohr*, 518 U.S. at 496-501.

Aquino cites several cases to this effect, arguing that because the BSC Device never received PMA, it was subject only to the 510(k) process, which did not impose any federal "requirements" to preempt her state claims. In response, BSC points out that its argument rests not on the 510(k) clearance its product initially received based on the incorporation of Marlex, but rather on the FDA Letter concerning the Chinese polypropylene BSC used later (and in Aquino's device). R. 85 at 2-3. BSC argues that as in the case of PMA, the FDA specifically ruled on the safety of the Chinese polypropylene through the FDA Letter, establishing "requirements" for purposes of Section 360k, and preempting Aquino's claims.

It isn't difficult to understand BSC's attraction to the argument. Indeed, the FDA Letter states that the "change in supplier" (from Phillips to EMAI) did not "raise new safety or effectiveness concerns," and did not require a new premarket notification despite the variability between the products. R. 72, Ex. 5 at 1. These

pronouncements—particularly when combined with the almost 18-month gap between the date of the Citizen Petition and the issuance of the FDA Letter—do tend to suggest that the FDA's analysis exceeded that required in a typical 510(k) equivalence review. And the Court acknowledges the possibility that something other than PMA could result in preemption under Section 360k. *See, e.g.*, *Eggerling v. Advanced Bionics, LLC*, 958 F. Supp. 2d 1029, 1036 (N.D. Iowa 2013) ("There is no requirement that a medical device be FDA-approved for preemption by the MDA to apply" (citing *Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 680-81 (W.D. Ky. 2013)). But the contours of any alternative bases for express preemption are unclear, and none of the cases BSC relies upon require it here.

BSC argues that *Kubicki ex rel. Kubicki v. Medtronic, Inc.*, 293 F. Supp. 3d 129 (D.D.C. 2018) supports the proposition that "FDA actions occurring after the FDA's decision to allow a manufacturer to sell a medical device" can trigger preemption. R. 92 at 2. *Kubicki* did involve a citizen petition, but the similarities to this case are superficial at best. There, the court held that the plaintiff's common law claims regarding an insulin pump were preempted because the pump was part of an insulin-delivery system that *itself received PMA*. 293 F. Supp. 3d at 173-76 (citing the MDA definition for "device" as including "any component, part, or accessory," 21 U.S.C. § 321(h)). Indeed, the FDA rejected the petition's request that it modify the PMA letter it had issued to indicate that PMA did not extend to the pump itself.[7] *Id.* at 175. Thus,

[7] Aquino's reliance on *Duggan v. Medtronic, Inc.*, 840 F. Supp. 2d 466 (D. Mass. 2012) and *Bentzley v. Medtronic, Inc.*, 827 F. Supp. 2d 443 (E.D. Pa. 2011)—which draw the same conclusions from the same citizen petition—is likewise unavailing.

the FDA's response was merely additional evidence to support express preemption *because of PMA*. Similarly, in *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001), the court held that plaintiff's failure to warn claim was preempted because not only had the product at issue been deemed to have received PMA (having undergone the similarly rigorous New Drug Application ("NDA") process that applied to medical devices prior to the enactment of the MDA), but also its labeling was "subject to meticulous and ongoing federal regulation." 273 F.3d at 788-99. By contrast, there can be no dispute that the BSC Device, Marlex, or Chinese polypropylene were ever subject to the PMA or NDA processes.

Instead, considering that the FDA Letter analyzed the use of Chinese polypropylene rather than Marlex—a product subject only to Section 510(k) review—the most that can be said at this stage is that the FDA's findings amount to an equivalence determination between the two. *See* R. 72, Ex. 5 at 1 (FDA Letter noting "we reviewed testing of the polypropylene raw material as well as the finished mesh . . . from both sources"); *see also Lohr*, 518 U.S. at 492 (510(k) equivalence determinations "simply compare a [new] device to [an existing] device to ascertain whether the later device is no more dangerous and less effective than the earlier device"). That is no comment on safety, and does not preempt Aquino's claims. *Id.* at 493 (510(k) approval provides "little protection to the public" because it is "focused on *equivalence*, not safety").

Implied preemption. Nor does the Court find BSC's implied preemption arguments persuasive. In *Mullins*—another pelvic mesh case in one of the MDLs

before Judge Goodwin—as here, the mesh received Section 510(k) clearance. 147 F. Supp. 3d at 485. And there, as here, the defendant argued for implied preemption. *Id.* The court held that the defendant's implied preemption arguments failed for the same reason its express preemption arguments did in cases before *Mullins* in the same MDL. Specifically, citing *Lohr*, the court noted that Congress's intent in creating the 510(k) process was two-fold: (1) to prevent manufacturers of already existing medical devices from monopolizing the market while new products waited to clear the PMA hurdle; and (2) to ensure that improvements to existing devices could be rapidly introduced. The court concluded that neither goal conflicted with the state law requirement of reasonable safety, and so the plaintiff's claims were not impliedly preempted. 147 F. Supp. 3d at 482-85; *see also Kaiser v. Johnson & Johnson*, 334 F. Supp. 3d 923, 936-37 (N.D. Ind. 2018) (no implied preemption because Congress did not intend in enacting Section 510(k) "to do anything other than maintain the status quo with respect to . . . existing medical devices and their substantial equivalents," which "included the possibility that the manufacturer . . . would have to defend itself against state-law claims of negligent design." (quoting *Lohr*, 518 U.S. at 494)). *Mullins* applies equally here, and BSC's argument fails for the same reasons its express preemption argument did. That is, the FDA Letter at best amounts to an equivalence determination between Marlex and the Chinese polypropylene, which cannot preempt Aquino's claims.

BSC nevertheless contends that Aquino's claims concerning the Chinese polypropylene constitute an improper attempt to privately enforce the FDCA akin to

the claims the Supreme Court held impliedly preempted in *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). But the Court is not persuaded. In *Buckman*, the defendants allegedly made false representations to the FDA in the course of obtaining approval to market a medical device, and the plaintiff brought state law fraud claims against it. The court held that "State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." 531 U.S. at 350. Here, although the SAC spends considerable space on allegations concerning BSC's allegedly improper use of Chinese polypropylene, Aquino argues and the Court agrees that her claims sound in negligence and strict liability—state law products liability claims regarding the use of polypropylene in Defendants' Mesh Products.[8] *Buckman* is therefore inapposite. *See id.* at 352-53 (distinguishing plaintiffs' state law fraud claims from the negligence and strict liability claims in *Lohr* and holding them impliedly preempted since "the existence of these federal enactments is a critical element in their case"); *see also Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010) (*Buckman* "specifically distinguished . . . 'fraud-on-the-agency' claims, *i.e.*, claims not related to a field of law that states had traditionally occupied, from claims based on state law tort principles").

[8] As noted, Aquino dropped her Illinois Counterfeit Trademark Act claims arising out of BSC's (and Cambridge's) conduct with respect to the Chinese polypropylene. While Aquino characterizes her remaining claims as "classic state product liability claims," she also contends that her Chinese polypropylene allegations are "relevant," "particularly to the willful and wanton misconduct claim." R. 81 at 19. The Court addresses Aquino's willful and wanton misconduct claims *infra*.

Accordingly, BSC's claims are neither expressly nor impliedly preempted. BSC may re-raise preemption on summary judgment if it concludes that it has a credible basis to do so (and Aquino sufficiently repleads her claims as described below).

2. Preclusion

BSC next argues that the conclusions in the FDA Letter have a preclusive effect over Aquino's claims even if they are not preempted. Citing *Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 922 (D.C. Cir. 2013), BSC characterizes Aquino's claims as a "request to review the FDA's findings" regarding the safety of the Chinese polypropylene—review that is appropriate only by Courts of Appeals under 21 U.S.C. § 360g(a) (providing for direct review of certain FDA decisions). R. 72 at 11-12. But the manufacturer in *Cytori* sought review of the FDA's rejection of its 510(k) submission. 715 F.3d at 923-25 (MDA provides for direct review by the D. C. Circuit of an FDA substantial equivalence determination). While the MDA does require a Court of Appeals to review such a decision, Aquino seeks no such review here.[9]

BSC also argues that deference to the FDA's conclusions is appropriate because the letter was the product of the FDA's scientific expertise and is consistent with the purpose of the doctrine of primary jurisdiction. But again, these arguments miss the point. Aquino is not asking for a review of the FDA's determinations regarding Chinese polypropylene; instead, Aquino seeks to recover for injuries sustained from the implantation of Defendants' polypropylene products, and the allegations about

[9] Her reliance on *Electromedical Products International, Inc. v. Kessler*, 949 F. Supp. 30 (D.C.C. 1997) fails for the same reason. 949 F. Supp. at 31-32 (district court lacked jurisdiction to review FDA decision to deny PMA).

Chinese polypropylene are relevant to the possible recovery of punitive damages. *See* R. 81 at 20-21 (Aquino's response brief stating that "it is plaintiff's position that *any polypropylene mesh* used in these products is unreasonably dangerous for implantation," and that allegations about the steps BSC took to obtain Chinese polypropylene "may be relevant . . . to the willful and wanton misconduct claim"). BSC's preclusion and deference arguments also fail.

C. Aquino's Causation Allegations Concerning Transvaginal Versus Transabdominal Mesh

BSC contends that Aquino's strict liability and negligence claims against it should be dismissed because the vast majority of the SAC's causation allegations refer generally to "Defendants' Mesh Products," and any factual support offered concerns trans*vaginal* rather than trans*abdominal* mesh. *See Bank of Am., N.A. v. Knight*, 725 F.3d 815, 818 (7th Cir. 2013) ("Each defendant is entitled to know what he or she did that is asserted to be wrongful. A complaint based on a theory of collective responsibility must be dismissed."); *see also Bowe v. Abbott Laboratories, Inc.*, 608 N.E.2d 223, 225 (Ill. App. Ct. 1992) ("A fundamental element in a negligence or strict liability action is the burden placed upon the plaintiff to identify the defendant who caused the alleged harm or injury." (citing *Smith v. Eli Lilly & Co.*, 560 N.E.2d 324 (Ill. 1990))). In response, Aquino argues that the SAC "sets forth more than sufficient factual allegations" to support her claims. But she nevertheless offers additional facts outside of the SAC, including the trial testimony of Aquino's treating physician Bruce Rosenzweig, M.D.—a urogynecologist at Rush University Medical Center—in *Tyree et al. v. Boston Scientific Corporation*, No. 12 C 8633 (S.D. W. Va.), another

transvaginal mesh case residing in one of the MDLs. *See* R. 81, Ex. 8. Aquino claims that this "factual elaboration" is not only permitted, but encouraged by the Seventh Circuit. R. 81 at 21-22.

Aquino is correct that the Seventh Circuit permits parties opposing motions to dismiss to "submit materials outside the pleadings to illustrate the facts the party expects to be able to prove." *Geinosky v. City of Chi.*, 675 F.3d 743, 745 n.1 (7th Cir. 2012); *Bishop v. Air Line Pilots Assoc., Int'l*, 900 F.3d 388, 399 n.28 (7th Cir. 2018) (accord). But such materials must be relevant to and consistent with the pleadings. *See In re Dealer Mgmt. Sys. Antitrust Litig.*, 313 F. Supp. 3d 931, 939 n.1 (N.D. Ill. 2018) (considering new factual allegations in opposition brief "*only* to the extent that they are relevant and actually consistent with the Complaint's allegations") (emphasis in original).

BSC argues that Aquino's "factual elaboration" is not relevant to her claims against it, because the deposition testimony and other "elaboration" offered—like the SAC itself—concern trans*vaginal* (the Bard Device), rather than trans*abdominal* (the BSC Device), mesh. *See* R. 85 at 4 (characterizing Dr. Rosenzweig's testimony as concerning "different devices packaged with different directions for use and implanted by a different method . . . in different patients at a different point in time."). The Court agrees. First, not once in its 64 pages does the SAC mention the abdomen, abdominal mesh, or the transabdominal placement of mesh. *See generally* SAC. And Aquino mentions that the BSC Device is transabdominal mesh just once in her brief, and then only in a footnote. There, she acknowledges that although the trial

testimony she offers concerns transvaginal mesh, Dr. Rosenzweig "opined that all polypropylene mesh is unsafe for implantation in the human body for reasons of deformation, shrinkage, degradation and difficulty/impossibility of total removal." R. 81 at 31, n.10. But this argument is belied by the fact that Dr. Rosenzweig emphasizes the unsuitability of the vagina for polypropylene mesh as compared to the abdomen in the same testimony. *See* R. 81, Ex. 8 at 75-78 (stating that the vagina treats polypropylene differently than the abdomen due to its "very high concentration of nerves," bacteria, and production of peroxide, the latter which degrades the polypropylene). But for a single reference in an attachment to Aquino's response brief,[10] Aquino's causation allegations specific to the BSC Device are nonexistent. *Cf. id.* ¶¶ 11-22 (discussing FDA and ACOG/AUGS warnings about dangers of transvaginally-placed mesh).

Aquino also argues that dismissal is not warranted because her claims "mirror the required MDL long form complaint." R. 81 at 2. But as noted, the MDLs also concern trans*vaginal* mesh. *See In re Boston Scientific Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, 2016 WL 3067796, at *1 (S.D. W. Va. May 31, 2016) ("This case resides in one of seven MDLs assigned to me . . . concerning the use of transvaginal surgical mesh"). And the distinction matters. In 2016, the FDA reclassified transvaginally-placed (but not transabdominally-placed) surgical mesh for POP repair from Class II to Class III. https://www.govinfo.gov/content/pkg/FR-2016-01-05/pdf/2015-33165.pdf

[10] *See* R. 81, Ex. 6 (summary of Aquino's May 18, 2018 appointment with Dr. Rosenzweig stating "[t]he root cause is the mesh placed more like the [Bard] Align with a contribution from the [BSC] Y-mesh.").

(last visited Sept. 6, 2019). Then, in April 2019, the FDA ordered manufacturers of surgical mesh intended for transvaginal repair of POP to stop selling and marketing their products, having determined that the manufacturers had not provided reasonable assurances of safety and efficacy. *See* https://www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants(last visited on Sept. 5, 2019). But in the same communication, the FDA stated that "the benefit-risk profile of mesh placed transabdominally to treat POP . . . remains favorable." *Id.* Materials quoted in the SAC also distinguish between the safety of the two types of mesh. *See, e.g.*, R. 72, Ex. 1 at 6, 11 (FDA White Paper describing "high success rates" for mesh placed transabdominally and that such mesh may result in "lower rates of mesh complications compared to transvaginal POP surgery with mesh.").[11] Accordingly, even considering Aquino's "factual elaboration," it is of no help to Aquino. Dismissal of Aquino's negligence and strict liability claims (Counts VIII-XI)—all of which require a plausible allegation of causation—is required.

D. Remaining Claims

BSC argues that Aquino fails to sufficiently plead her breach of express warranty claim against it, and that a willful and wanton misconduct claim is unavailable to her as a matter of law.

Breach of Express Warranty (Count XII). BSC contends that Aquino's breach of express warranty claim against it fails because the SAC does not allege any

[11] Further, while numerous cases have been filed regarding transvaginal mesh, the Court had difficulty finding even a single case involving a transabdominal mesh product.

specific affirmative statement BSC made, and nor does it allege privity of contract or reliance by Aquino on supposed statements by BSC. To state a claim for breach of express warranty in Illinois, plaintiffs must allege that the seller: (1) made an affirmation of fact or promise; (2) relating to the goods; (3) which was part of the basis for the bargain; and (4) guaranteed that the goods would conform to the affirmation or promise. *Kmak v. Sorin Grp. Deutschland GmbH*, 2017 WL 8199974, at *5 (N.D. Ill. Dec. 12, 2017) (citing 810 ILCS 5/2-313(1)(a)). Although generally there must also be privity of contract, *id.* (citing *Canadian Pac. Ry. Co. v. Williams-Hayward Protective Coatings*, 2005 WL 782698, at *15 (N.D. Ill. Apr. 6, 2005)), an exception exists when a manufacturer "expressly warranted its goods to the ultimate consumers and this was the basis for the bargain and relied upon by plaintiffs." *In re McDonald's French Fries Litig.*, 503 F. Supp. 2d 953, 957 (N.D. Ill. 2007); *see also Rosenstern v. Allergan, Inc.*, 987 F. Supp. 2d 795, 805 (N.D. Ill. 2013) ("manufacturer documents given directly to the buyer . . . may give rise to an express warranty because the assertions become part of the basis of the bargain unless clear affirmative proof shows otherwise" (quoting *Williams-Hayward Protective Coatings*, 2005 WL 782698, at *15)).

A plaintiff alleging breach of express warranty must also "state the terms of the warranty or attach it to the complaint." *Baldwin v. Star Sci., Inc.*, 78 F. Supp. 3d 724, 739 (N.D. Ill. 2015). "Failure to do so renders the claims invalid." *N. Ins. Co. of N.Y. v. Silverton Marine Corp.*, 2010 WL 2574225, at *2 (N.D. Ill. June 23, 2010) (dismissing breach of express warranty claim for plaintiff's failure to attach warranty

to complaint or state its terms). Aquino has done neither. The SAC does allege that "Defendants' Mesh Products . . . have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective . . . surgical techniques" and as "safer and more effective as compared to available feasible alternative treatments." SAC ¶ 31. It also alleges that BSC "made assurances" to that effect to the "general public, hospitals and health care professionals." *Id.* ¶ 141. But such allegations do not suffice. *See, e.g., Griffin v. Medtronic, Inc.*, 2017 WL 4417821, at *5 (N.D. Ill. Oct. 5, 2017) (allegation that defendant expressly warranted that product was "safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal compared to other . . . products, and that it was adequately tested and fit for its intended use" were "conclusory" and failed to "give notice to [defendant] of the claimed warranty"); *Heisner ex rel. Heisner v. Genzyme Corp.*, 2008 WL 2940811, at *8-9 (N.D. Ill. July 25, 2008) (allegation that defendant stated "orally and in publications, package inserts, and other written materials" that product was "safe, effective, fit and proper for its intended use" was insufficient to support breach of express warranty claim).

Nor can Aquino establish privity or its exception. Indeed, Aquino does not allege that she purchased anything from either BSC or a "dealer." *Rosenstern*, 987 F. Supp. 2d at 805 (privity exception available only "[i]n the context of a buyer purchasing a product from a dealer" (quoting *Williams-Hayward Protective Coatings*, 2005 WL 782698, at *15)). Rather, she alleges only that she was implanted with the BSC Device "at Mercy Hospital and Medical Center, Chicago, Illinois." SAC ¶ 3. Thus,

Aquino was not a "buyer" at all. Count XII is dismissed. *Kmak*, 2017 WL 8199974, at *5 (dismissing breach of express warranty claim because plaintiff did not "allege that she bought anything—either from a manufacturer or any dealer. The [medical device] was used during [plaintiff's] surgery.").

2. Willful and Wanton Misconduct (Count XIV)

Finally, BSC argues that Count XIV must be dismissed because willful and wanton misconduct is not a recognized tort in Illinois. The Court agrees, at least with respect to Defendants and other private entities and individuals. Courts in this district have noted "lingering confusion" on the availability of willful and wanton misconduct as a standalone claim in Illinois. *Gordon v. Devine*, 2008 WL 4594354, at *8-9 (N.D. Ill. Oct. 14, 2008) (citing *Allen v. City of Zion*, 2003 WL 22078374, *3 (N.D. Ill. Sept. 3, 2003)). Such confusion arose in large part from trying to reconcile Section 2-202 of Illinois's Local Governmental and Governmental Employees Tort Immunity Act with cases holding that willful and wanton conduct is not a separate tort. *Compare* 745 ILCS 10/2-202 ("A public employee is not liable for his act or omission in the execution or enforcement of any law unless such act or omission constitutes *willful and wanton conduct*." (emphasis added)), *with Ziarko v. Soo Line R.R.*, 641 N.E.2d 402, 406 (Ill. 1994) ("There is no separate and independent tort of 'willful and wanton' misconduct"). The Court is persuaded by those courts that have resolved the confusion by acknowledging the viability of such a claim against public officials, employees and entities, but not private individuals and entities. *See, e.g.*, *Gordon*, 2008 WL 4594354 at *8 ("We find that this conflict can be reconciled by permitting a

claim for 'wanton and willful misconduct' against a public official, but not a private individual" (collecting cases)); *Owens v. Fleet Car Lease, Inc.*, 2010 WL 11566100, at *2 (S.D. Ill. Jan. 15, 2010) ("this conflict is best resolved by permitting a claim for 'wanton and willful misconduct' to proceed against a governmental entity, public official or employee but not against a private individual or entity").

Illinois courts have also held that willful and wanton conduct may justify punitive damages—including against private individuals and entities—when tied to a recognized tort. *See Muniz v. Rexnord Corp.*, 2006 WL 1430553, at *2 (N.D. Ill. May 17, 2006) ("Plaintiffs can recover punitive damages based on willful and wanton misconduct if the . . . allegations are incorporated as part of a separate count containing a recognized tort"); *Mercury Skyline Yacht Charters v. Dave Matthews Band, Inc.*, 2005 WL 3159680, at *10 (N.D. Ill. Nov. 22, 2005) ("willful and wanton conduct typically is alleged in conjunction with both intentional torts and negligence to support a claim for punitive damages."). But the possibility of a punitive award cannot save Aquino's standalone claim. *See Corwin v. Connecticut Valley Arms, Inc.*, 74 F. Supp. 3d 883, 893 (N.D. Ill. 2014) ("The Illinois Supreme Court has explained that 'a prayer for punitive damages is not, itself, a cause of action,' but instead is a 'type of remedy.'" (quoting *Vincent v. Alden-Park Strathmoor, Inc.*, 948 N.E.2d 610, 615 (Ill. 2011))). Accordingly, Count XIV is also dismissed.

II. Bard's Motion to Dismiss

Bard does not take issue with Aquino's design defect claims, but argues that dismissal is appropriate as to Aquino's manufacturing defect, failure to warn, and

breach of express warranty claims because she fails to sufficiently plead them. The Court addresses them in turn.

A. Manufacturing Defect Claims (Counts I and III)

Bard contends that Aquino's manufacturing defect claims in Counts I (negligence) and III (strict liability) fail because according to her brief, they are founded on Bard's use of Chinese polypropylene—an allegation that runs contrary to the SAC, which alleges that BSC, not Bard, used it. The Court agrees. Indeed, Aquino includes as "factual elaboration" in her brief an excerpt of trial testimony in another pelvic mesh case concerning a manufacturing method that causes fraying. R. 81 at 29. She argues that between this "elaboration" and the allegations in the SAC, it is clear that Bard "sourced non-Phillips polypropylene," "rais[ing] the issue of whether that change in manufacturing specification led to a manufacturing defect that increased the rate of degradation." *Id.* at 30. But in contrast, the SAC alleges that Bard "arrang[ed] for the purchase of *Marlex* . . . by third party companies, including Red Oaks, who then supplied Bard with the *Marlex*." SAC ¶ 62 (emphasis added). In other words, the Chinese polypropylene allegations do not implicate Bard, because according to Aquino's own allegations, Bard did not use or purchase Chinese polypropylene.[12] Aquino's manufacturing defect claims are dismissed.

[12] The "factual elaboration" gives the Court pause for the additional reasons that: (1) the testimony offered pertains to a different product manufactured by a different company; and (2) concerns the manufacturing process in general, as opposed to issues occurring in a specific device. *See Blue v. Envtl. Eng'g, Inc.*, 828 N.E.2d 1128, 1137 (Ill. 2005) ("A manufacturing defect differs from a design defect in that the former occurs in only a small percentage of units in a product line").

B. Failure to Warn (Counts I and IV)

Bard contends that Aquino's failure to warn claims (sounding in negligence and strict liability) are likewise deficient because: (1) under the learned-intermediary doctrine, Bard had no duty to warn Aquino directly of any risks associated with its product; and (2) to the extent Aquino's claims assert a breach of a duty to warn Aquino's physicians, they are inadequately plead.

But as a preliminary matter, Bard argues that Aquino's claims fail to the extent they concern Bard's failure to warn Aquino about the risks associated with Chinese polypropylene. *See* SAC ¶ 130(a) (alleging Bard failed to warn or instruct Aquino of the "[Chinese polypropylene]'s weaker fibers with molecular variations."). The Court agrees and Aquino does not argue otherwise. Nor could she; as noted, the SAC elsewhere makes clear that Bard purchased *Marlex* from third parties when Phillips stopped selling it to Bard directly. SAC ¶ 62. No duty ran from Bard to Aquino to warn of risks associated with a material it did not use.

Further, Bard is correct that under the learned-intermediary doctrine, a manufacturer has no duty to warn patients directly of the risks of prescription medical products so long as it provides sufficient warnings to the physician. *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 393 (Ill. 1987); *see also In re Zimmer, NexGen Knee Implant Prods. Liability Lit.*, 884 F.3d 746, 750 (7th Cir. 2018) ("the manufacturer of a medical device has no duty to warn the patient as long as the manufacturer provides adequate warnings to the physician"). The doctrine applies "forcefully in cases involving surgical implants" because it is "not reasonably

conceivable" that a patient could "obtain and implant a device . . . without . . . a physician." *In re Zimmer, NexGen Knee Implant Prods. Liab. Lit.*, 884 F.3d at 752 (quoting *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1368 (S.D. Fla. 2007)). Aquino does not (and cannot) dispute the implications of the learned-intermediary doctrine. Accordingly, Aquino's failure to warn claims fail to the extent they concern a duty running directly from Bard to Aquino. *See In re Zimmer, NexGen Knee Implant Prods. Liab. Lit.*, 884 F.3d at 752 ("to the extent that [plaintiff's] defective-warning claim is based on [defendant's] duty to warn *him*, it is foreclosed by the learned-intermediary doctrine").

Further, a manufacturer's duty to warn physicians is limited and does not extend to risks already known to the medical community. *See Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002) ("A corollary of [the learned intermediary] doctrine is the principle that a . . . manufacturer need not provide a warning of risks already known to the medical community."). Here, Aquino does not allege either what her surgeon knew generally as a member of the medical community, or what Bard warned her surgeon of specifically. And neither the SAC nor Aquino's brief provide any information about the warnings Bard gave.[13]

[13] Aquino points to the trial testimony of Dr. Rosenzweig in *Tyree*, arguing that the medical community was not aware of the potential for transvaginal mesh to deform, shrink, degrade or band, and nor was it aware that complete removal of the mesh may be impossible (risks that the SAC alleges Bard did not disclose). R. 81 at 31-34, 36. But this testimony does not square with the 2011 FDA Safety Communication and White Paper and the 2011 ACOG/AUGS Joint Committee Opinion referenced in the SAC, which make clear that some risks associated with transvaginal mesh were known or knowable as early as 5 years before Aquino's surgery—at least with respect to transvaginal mesh for POP repair. *See* SAC ¶¶ 11-12, 15-18, 20 (quoting the 2011

But even assuming some of the risks about which Aquino complains were neither warned of by Bard nor known by the medical community generally, Aquino still must allege that if there had been a proper warning, her surgeon would have declined to use the product. *See In re Zimmer, NexGen Knee Implant Prods. Liab. Lit.*, 884 F.3d at 752 (a plaintiff who establishes a duty and failure to warn must show that "if properly warned, he or she would have altered behavior and avoided injury"); *see also Rosenstern*, 987 F. Supp. 2d at 801-02 (allegations were sufficient including because plaintiff alleged that "[i]f [defendant] had informed [plaintiff] or her health care providers of the known risks," "they would have refused to use" the product). She does not. Accordingly, Aquino's failure to warn claims fail.

C. Breach of Express Warranty (Count V)

Bard argues that dismissal of Aquino's breach of express warranty claim against it is proper because: (1) Aquino is not in privity with Bard; (2) Aquino failed to attach the warranty upon which its claims are based or sufficiently state the terms of the warranty; and (3) Aquino did not satisfy the pre-suit notice requirement under the Illinois Uniform Commercial Code ("UCC").

Aquino's breach of express warranty claim against Bard fails for the same reasons it did as to BSC. First, Aquino fails to attach or state the terms of the warranty she contends Bard made, alleging only that Bard "made assurances . . . to the general public, hospitals and health care professionals that its mesh products

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FDA Safety Communication, FDA White Paper and ACOG/AGUS Joint Committee Opinion, which warned of "serious complications," including mesh contraction, retraction and shrinkage, and vaginal shortening, tightening and intractable pain).

were safe and reasonably fit for their intended purposes." SAC ¶ 141. As discussed, this is not enough. *See, e.g.*, *Griffin*, 2017 WL 4417821, at *5 (allegation that defendant warranted that product was "safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal comparable to other . . . products, and that it was adequately tested and fit for its intended use" failed to "give notice to [defendant] of the claimed warranty"). Nor does the "factual elaboration" Aquino adds by way of her response brief help. There, Aquino alleges that a 2012 Bard brochure claimed that "[t]he combination of stability and tension-free, self-anchoring support means resistance to deformation during placement." R. 81, Ex. 10. But an assertion that the device is "resistant" to a particular issue does not mean that the issue will not occur. Further, the statement relates only to the device's propensity to deform during *placement*, not after insertion. This is not enough. Finally, any privity argument also fails, because, as in *Kmak*, Aquino "does not allege that she bought anything—either from a manufacturer or a dealer. 2017 WL 8199974, at *5. Count V is dismissed.[14]

D. Willful and Wanton Conduct (Count VII)

Lastly, Bard argues that Aquino's "willful and wanton misconduct" claim fails as a matter of law because there is no such standalone claim for relief in Illinois. R. 73 at 12-13; R. 86 at 8-10. Bard is a private entity. Accordingly, this claim fails for the same reasons it failed against BSC.

[14] Because the Court finds dismissal is proper both for failure to allege the terms of the warranty and for lack of privity, it declines to also address Bard's UCC argument.

III. Cambridge's Motion to Dismiss

Cambridge argues that Aquino has failed to plausibly allege her negligence claim against it and that Aquino's claim of willful and wanton misconduct fails because it is not recognized as a separate tort in Illinois. The Court addresses each argument below.

A. Negligence (Count XV)

Count XV purports to state a claim against Cambridge for negligence in testing, failing to warn Aquino and/or her health care providers of the risks of the BSC Device, and causing the BSC Device to be unreasonably dangerous. In her response brief, Aquino recharacterizes the claim as based on Cambridge's "failure to properly inspect, examine and test the Chinese resin." R. 81 at 42. And this makes sense: Aquino's factual allegations as to Cambridge are limited to its 2011 testing of the Chinese polypropylene compared to Marlex, and removal of language from its initial report to BSC referring to the selenium it detected as "rare and toxic" and recommending further testing (but not the reference to selenium itself). *Id.* ¶¶ 103-110. Cambridge contends that Aquino has failed to allege sufficient facts to support any of the elements of negligence: duty, breach and proximate cause. *Simpkins v. CSX Transp., Inc.*, 965 N.E.2d 1092, 1096 (Ill. 2012). The Court notes at the outset the dispute over whether the Chinese polypropylene rendered the BSC Device more dangerous than it was when constructed with Marlex. But even assuming it did, as explained below, Aquino has failed to state a plausible claim against Cambridge.

Duty. First, Bard argues that Aquino has failed to plausibly allege a duty running from Cambridge to her. Whether a duty exists is a question of law for the court. *See Neumann v. Borg-Warner Morse Tec LLC*, 168 F. Supp. 3d 1116, 1120 (N.D. Ill. 2016) (citing *Simpkins*, 965 N.E.2d at 1096-97). Under Illinois law, "every person owes a duty of ordinary care to all others to guard against injuries which naturally flow as a reasonably probable and foreseeable consequence of an act." *Simpkins*, 965 N.E.2d at 1097 (quoting *Widlowski v. Durkee Foods*, 562 N.E.2d 967, 968 (Ill. 1990)). "[S]uch a duty . . . extends to remote and unknown persons," but is limited by four considerations: (1) the reasonable foreseeability of the injury; (2) the likelihood of the injury; (3) the magnitude of the burden of guarding against the injury; and (4) the consequences of placing that burden on the defendant." *Id.* Foreseeability is "a necessary factor for finding duty." *Id.* at 1098. Indeed, "[i]f the injury was not foreseeable, no duty can exist." *Id.*

Here, Cambridge clearly owed a duty to BSC to conduct testing and accurately report the results as requested. But finding a duty running from Cambridge to Aquino is more difficult, including because the SAC does not allege that Cambridge's reports were sent to or relied upon by any person or entity other than BSC, and nor does it allege that Cambridge understood the purpose of the testing. Aquino points to the 1964 Illinois Supreme Court opinion in *Nelson v. Union Wire Rope Corporation*, 199 N.E.2d 769 (Ill. 1964), arguing that *Nelson* demonstrates the "existence of a duty undertaken by a company performing safety testing and liability to those reasonably foreseeably injured by the negligent performance of that testing." R. 81 at 44-45.

Nelson, which applied Florida law, concerned 18 plaintiffs injured or killed when an elevator at a Florida construction site fell. 199 N.E.2d at 772. The plaintiffs were employees of a general contractor or its subcontractor, and the defendant was the general contractor's workmen's compensation and public liability insurance company. *Id.* The jury found that the insurance company undertook a voluntary duty running to both the general contractor and the plaintiffs to ensure the safety of the elevator by conducting periodic inspections. The court agreed, reasoning that defendant's safety engineers and the "financial and safety benefits claimed to inure to insureds as a result of their . . . services, were [the defendant's] chief stock in trade." *Id.* at 776.

But unlike the defendant in *Nelson*, ensuring the safety and efficacy of BSC's mesh products and the patients implanted with them was not Cambridge's "chief stock in trade." Instead, Cambridge's role was to conduct testing on two different materials and report the results to BSC—a role which, as discussed below, according to the SAC and in contrast to the defendant in *Nelson*, it fulfilled. Aquino argues that Cambridge must have known that the polypropylene it tested was for use in human bodies since BSC is "one of the world's largest manufacturers of resin based implantable mesh devices." R. 81 at 43. But even if true and that argument is properly considered at this stage, there is no allegation that Cambridge understood that BSC was considering using the Chinese polypropylene instead of Marlex, nor even *where* in the body the polypropylene would be placed. And as discussed *supra*, that fact

matters.[15] *Cf. Nelson*, 199 N.E.2d at 783 (finding support for jury conclusion that defendant knew personnel would ride elevator, because witnesses testified that defendant's engineer himself rode it, and that workers rode it regularly during his inspections). Accordingly, it is difficult to conclude that Aquino's injury was foreseeable to Cambridge at the time of testing. *Simpkins*, 965 N.E.2d at 1028 (foreseeability is examined from the perspective "at the time defendant engaged in the allegedly negligent action").

Breach. But even assuming a duty to Aquino did exist, the SAC does not allege a breach of that duty. While Aquino does allege that Cambridge failed to perform its tests in accordance with industry standards, SAC ¶ 103, she does not allege that had it done so, the results would have been different. *See Blue*, 828 N.E.2d at 1137 (plaintiff must plead both a standard of care and that defendant's deviation therefrom created the risk of harm at issue). Nor has she alleged that the results Cambridge produced were inaccurate in any way. In fact, her claim hinges on Cambridge's removal of language related to the selenium its testing revealed. And Cambridge's removal of that language—that is, that selenium was "rare and toxic," and that the result warranted further testing—also was no breach. According to the SAC, Cambridge provided the information to BSC before its removal. SAC ¶¶ 106-108. But what BSC did with that information is not attributable to Cambridge. And as noted

[15] Aquino's argument is further belied by the fact that BSC's website lists over 70 different categories of products that it develops, manufactures and distributes. https://www.bostonscientific.com/content/gwc/en-US/products.html (last visited on Sept. 9, 2019).

Aquino does not allege that Cambridge's reports were received or relied upon by any person or entity other than BSC.[16] Aquino has not alleged a breach of any duty.

Proximate Cause. Finally, Cambridge contends that Aquino fails to plausibly allege that its testing was a proximate cause of her injuries. To establish proximate cause, a plaintiff must allege facts that, if proven, establish both cause in fact and legal cause. *City of Chi. v. Beretta USA Corp.*, 821 N.E.2d 1099, 1127 (Ill. 2004). Cause in fact exists "when there is a reasonable certainty that a defendant's acts caused the injury or damage." *Young v. Bryco Arms*, 821 N.E.2d 1078, 1085 (Ill. 2004) (quoting *Lee v. CTA*, 605 N.E.2d 493 (1992)). "In deciding this question, we first ask whether the injury would have occurred absent the defendant's conduct." *Id.* Where "there are multiple factors that may have been combined to cause the injury, we ask whether defendant's conduct was a material element and a substantial factor in bringing about the injury." *Id.* Aquino alleges that Cambridge "detected the toxic element selenium" in the Chinese polypropylene, and "participated in the distribution of [the Chinese polypropylene] for production in the BSC mesh products]. SAC ¶¶ 8, 73. But Aquino does not allege that Cambridge's testing had any effect on BSC's decision to use non-Marlex polypropylene in the manufacture of its device, and fails to put forth any facts to plausibly allege that it was involved in the distribution of BSC's products.

[16] The Court is baffled by any suggestion that the removal of the characterization of selenium as "rare and toxic"—but not the removal of the reference to selenium itself—would constitute a breach even if that characterization had never been shared with BSC. Selenium is widely understood to be toxic. *See, e.g.*, https://en.wikipedia.org/wiki/Selenium (last visited on Sept. 18, 2019) (selenium is toxic if taken in excess).

Accordingly, Cambridge's conduct was neither a material element nor a substantial factor causing Aquino's injury.

Moreover, legal cause exists "only if the defendant's conduct is 'so closely tied to the plaintiff's injury that he should be held legally responsible for it.'" *Beretta USA Corp.*, 821 N.E.2d at 1127 (quoting *McCraw v. Cegielski*, 680 N.E.2d 394, 396 (Ill. App. Ct. 1996)). The inquiry "involves an assessment of foreseeability, in which we ask whether the injury is of a type that a reasonable person would see as a likely result of his conduct." *Id.* "If the defendant's conduct is so remote from the events leading to a plaintiff's injury that it can be said, as a matter of law, such conduct was not a contributing legal cause, the defendant is not liable." *Watson v. Enter. Leasing, Co.*, 757 N.E.2d 604, 611 (Ill. App. Ct. 2001). Here, as discussed, Aquino fails to plead sufficient facts to demonstrate foreseeability. And not only did Cambridge's testing occur 5 years prior to Aquino's implantation procedure, but also BSC used another company to test the same materials mere months before Aquino's surgery. SAC ¶¶ 119-23. Accordingly, Aquino has failed to allege that Cambridge's conduct was the proximate cause of her injuries, and failed to plausibly allege a negligence claim against Cambridge. Count XV is dismissed.

B. Willful and Wanton Misconduct (Count XVI)

Count XVI purports to state a claim for willful and wanton misconduct against Cambridge. As discussed, such an action is not cognizable against a private entity. Count XVI is dismissed.[17]

CONCLUSION

For the foregoing reasons, BSC's motion to dismiss is granted, R. 70, Bard's partial motion to dismiss is granted, R. 71, and Cambridge's motion to dismiss is granted, R. 76. Only Aquino's design defect claims as to Bard (Counts I and II) remain. If Aquino believes she can cure the deficiencies identified here, she may move for leave to file an amended complaint on or before October 18, 2019. The motion should attach a redlined comparison between the SAC and the proposed third amended complaint, and be supported by a brief of no more than ten pages describing how the proposed amended complaint cures the deficiencies in the SAC.

ENTERED:

Thomas M Durkin

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Honorable Thomas M. Durkin
United States District Judge

Dated: September 19, 2019

[17] As noted, Cambridge also joined in BSC's preemption and preclusion arguments. Those arguments fail for the reasons stated *supra*, and do not provide an independent basis for dismissing Aquino's negligence claim against Cambridge.